

REMARKS

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and the following remarks.

I. **Introductory Remarks**

Upon entry of the foregoing amendments, claims 52-53 and 56-63 will be pending in the application. Claims 52, 56, 60 and 62-63 are being amended, but the amendments introduce no new subject matter into the application. Claims 56 and 60 are merely rewritten in independent form, while claims 62-63 are amended only to change their dependency. Claims 15, 28, 31-35 and 54 are being canceled without prejudice or disclaimer.

II. **Allowability of Claims 56-61**

Claims 56-61 were objected to for being dependent upon a rejected base claim, but the Examiner indicated that they would be allowable if rewritten in independent form. Applicants have adopted the suggestion to rewrite these claims in independent form, and therefore request allowance of the claims.

III. **The Claims are Non-Obvious**

Claims 1, 15, 28, 31-35 and 62-63 were rejected under 35 U.S.C. § 103 as allegedly being obvious over Levy (U.S. Patent No. 5,283,255) and Richter (U.S. Patent No. 5,705,518). Applicants respectfully traverse the rejection.

Obviousness requires a reasonable likelihood of success for practicing the invention, but such a likelihood did not previously exist for the presently claimed invention. As explained in Applicants' prior response, nail infections are notoriously difficult to treat. *See*, Campbell et al., stating, "[o]nychomycosis is a common nail disease responsible for approximately 50% of disease of the nail . . . the diagnosis and treatments are difficult and the choice of appropriate antifungal drugs complex and require the knowledge of the chemical structures of the metabolites of the molds that cause onychomycosis and their interaction with the antifungal drugs" (Abstract, Scientific World Journal, 2004 Aug 31; 4; 760-777) (already of record). *See, also* Gupta et al. stating, "[o]nychomycosis is a fungal infection affecting the

nail bed and nail plate; it may be chronic and can be difficult to treat” (Abstract, Am. J. Clin. Dermatol. 2004; 5(4); 225-37) (already of record). In addition, Albert et al. recognize the difficulty in treating onychomycosis, where they state, “[o]f all superficial fungal infections, onychomycosis is the most difficult to manage. Practitioners of all disciplines realize its chronic nature, difficulty in eradication and propensity to recur” (Abstract, Clin. Podiatr. Med. Surg. 2004 Oct. 21(4); 605-15) (already of record). Omero et al. support this proposition, “[o]nychomycosis--the dermatophytic invasion of the nail--is difficult to eradicate with drug treatment” (Abstract, Mycopathologia, 2004 Aug; 158(2): 173-80) (already of record).

Each of the references cited above was published in 2004, several years after the present application was filed. Since the level of skill in the art is ever expanding and not contracting, the references establish that at the time of Applicants’ filing, one skilled in the art would have understood that treating onychomycosis is quite difficult.

Only recently have studies been performed directed to the use of photodynamic therapy for treatment of the dermatophyte *Trichophyton*, one of the fungi which can cause onychomycosis.¹ Smijs et al. disclose using porphyrins for photodynamic killing of the dermatophyte. In fact, Smijs states, “[t]he present study shows that *Trichophyton rubrum* in suspension culture is susceptible to photodynamic treatment, a completely new application in this area.” (Photochem. Photobiol 2003 May; 77(5); 556-60, abstract) (already of record). In a later publication also by Smijs, he states, “[t]he application to photosensitizers for the treatment of fungal infections is a new and promising development within the field of photodynamic therapy.” (Photochem. Photobiol 2004 Sep-Oct; 80(2): 197-202, abstract) (already of record).

¹ The primary fungi that cause onychomycosis are *trichophyton rubrum* and *trichophyton mentagrophytes*. They are dermatophytes (fungi that infect hair, skin, and nails) and feed on keratinized (nail) tissue. The infections they cause are normally confined to the nails, but occasionally spread to the surrounding skin. Another type of onychomycosis is caused by yeast (*candida albicans* or *candida parapsilosis*). These infections are less common but produce similar symptoms. See <http://www.podiatrychannel.com/onychomycosis>

Given the notorious difficulty of treating nail fungus at the time this application was filed, the Examiner's interpretation of Levy and Richer to establish that the claimed invention is *prima facie* obvious is improper and based on hindsight knowledge. Accordingly, Applicants respectfully request withdrawal of the obviousness rejection.

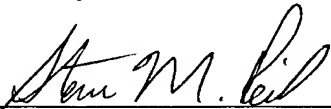
IV. Concluding Comments

This application is now in condition for allowance, and favorable reconsideration of it is respectfully requested.

If the Examiner believes that an interview would further advance prosecution of the application, he or she is invited to contact the undersigned attorney by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

By 

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